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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/401,636 09/22/99 HELLMAN

L 10223/006001

EXAMINER

HM22/0102

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ART UNIT

PAPER NUMBER

1644

DATE MAILED:

13

01/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/401,636

Applicant(s)
Hellman

Examiner
Gerald Ewoldt

Group Art Unit
1644

☒ Responsive to communication(s) filed on Oct 18, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 2, and 4-11 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, and 4-11 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10, 12

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claims 1, 2, and 4-11 are pending and being acted upon.
2. In view of Applicant's amendment and arguments, filed 10/18/00, only the following rejections remain.
3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 1, 2, and 4-11 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "An immunogenic polypeptide comprising a nonself IgE CH2 domain, a self IgE CH3 domain, and a nonself IgE CH4 domain" does not reasonably provide enablement for:
 - A) "An immunogenic polypeptide comprising a self IgE portion and a nonself IgE portion, and wherein said self IgE portion comprises at least a portion of a CH3 domain of IgE" (claim 1).
 - B) "The immunogenic polypeptide of claim 1 wherein the nonself portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said nonself IgE portion," (claim 5).
 - C) "The immunogenic polypeptide of claim 5, wherein said first region comprises at least a portion of an IgE CH2 domain (claim 6).
 - D) "The immunogenic polypeptide of claim 5, wherein said first region comprises at least a portion of an IgE CH4 domain (claim 7).

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed in claims 1, 5, 6, and 7 without an undue amount of experimentation. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the efficacy of an immunogenic polypeptide that lacks the minimal IgE-receptor binding domain, for the treatment IgE related diseases. The claimed terms "portion", "at least a portion", and "region" are open-ended and include an unlimited number of fragments of various sizes, including single amino acids, of the recited CH domains. The specification discloses functional activity for a single, complete polypeptide comprising a nonself IgE CH2 domain, a self IgE CH3 domain, and a nonself IgE CH4

domain only. The specification fails to disclose any fragments, portions, or regions that are effective for the generation of antibodies for the treatment IgE related diseases. The problem of predicting which fragments of a protein will retain functionality and which will not is unpredictable, complex and well outside the realm of routine experimentation. *In re Fisher*, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Applicant's arguments, filed 10/18/00, have been fully considered but they are not persuasive. Applicant argues that a person of ordinary skill in the art at the time of the invention could have followed the teachings of Examples 1 and 2 in the specification to make and use the immunogenic peptides as claimed. However, Examples 1 and 2 disclose only a single construct and offer no teachings as to how said construct might be modified while retaining activity. Specifically, the specification provides no guidance as to which portions of the construct might be removed while retaining activity. Applicant further argues that the prior art is incorrect as to the location of the IgE high-affinity receptor binding site. However, said argument offers no insight as to what portion of Applicant's construct is unnecessary for function in the claimed invention.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 4-7, and 11 stand rejected under 35 U.S.C. 102(b) as being anticipated by EP 0327378 (1989, IDS, of record) for the reasons of record set forth in paper No. 9, mailed 7/3/00.

Applicant's arguments, filed 10/18/00, have been fully considered but they are not persuasive. Applicant argues that the reference does not disclose the claimed polypeptide

containing a non-self IgE portion and at least a portion of a self CH3 domain of IgE. However, the reference teaches a construct comprising IgE including a CH3 domain from the same or different species, thus the reference anticipates the claim. As a product cannot be separated from its properties, the polypeptide of the reference has the immunogenic properties of the product of the instant claims.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1 and 8-9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 0327378 for the reasons of record set forth in paper No. 9, mailed 7/3/00.

Applicant's arguments, filed 10/18/00, have been fully considered but they are not persuasive. Applicant argues that the reference does not disclose the immunogenic polypeptide of the instant claims. However, as described supra, a product cannot be separated from its properties, therefore, the polypeptide of the reference has the immunogenic properties of the product of the instant claims.

9. No claim is allowed.

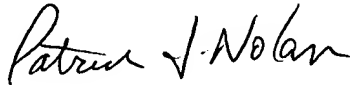
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
December 26, 2000


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